

**TOPCARE 8 HOUR PAIN RELIEF- acetaminophen tablet, film coated, extended release**  
**Topco Associates LLC**

-----  
**Topco Associates LLC. 8 Hour Pain Relief Drug Facts**

**Active ingredient (in each caplet)**

Acetaminophen 650 mg

**Purpose**

Pain reliever/fever reducer

**Uses**

- temporarily relieves minor aches and pains due to:
- muscular aches
- backache
- minor pain of arthritis
- toothache
- premenstrual and menstrual cramps
- headache
- the common cold
- temporarily reduces fever

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product

**Ask a doctor before use if you have**

liver disease

**Ask a doctor or pharmacist before use if you are**  
taking the blood thinning drug warfarin

**Stop use and ask a doctor if**

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition.

**If pregnant or breast-feeding,**  
ask a health professional before use.

**Keep out of reach of children.**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

- **do not take more than directed (see overdose warning)**

adults and children 12 years and over	<ul style="list-style-type: none"><li>• take 2 caplets every 8 hours with water</li><li>• swallow whole; do not crush, chew, split or dissolve</li><li>• do not take more than 6 caplets in 24 hours</li><li>• do not use for more than 10 days unless directed by a doctor</li></ul>
children under 12 years	<ul style="list-style-type: none"><li>• do not use</li></ul>

**Other information**

- store at 20-25°C (68-77°F)
- **do not use if printed foil under cap is broken or missing**
- meets the requirements of USP Dissolution Test 2

**Inactive ingredients**

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized

starch, stearic acid, titanium dioxide

## Questions or comments?

1-888-423-0139

### Package/Label Principal Display Panel

COMPARE TO TYLENOL® 8HR ACTIVE INGREDIENT

8 HR Pain Relief

ACETAMINOPHEN EXTENDED-RELEASE TABLETS, 650 mg

PAIN RELIEVER - FEVER REDUCER

OUR PHARMACISTS RECOMMEND

8 HOUR

For up to 8 Hours Relief of Minor Muscle Aches and Pain

actual size

100 CAPLETS† - 650 mg EACH

†CAPSULE-SHAPED TABLETS



DISTRIBUTED BY TOPCO ASSOCIATES LLC  
 ELK GROVE VILLAGE, IL 60007  
 ©TOPCO PERA0819 QUESTIONS? 1-888-423-0139  
 topcare@topco.com www.topcarebrand.com



This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

\* This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® 8HR.



Scan here for more information

**Drug Facts**

**Active ingredient (in each caplet) Purpose**  
 Acetaminophen 650 mg..... Pain reliever/fever reducer

**Uses**

- temporarily relieves minor aches and pains due to:
  - muscular aches      ■ backache
  - minor pain of arthritis    ■ toothache
  - premenstrual and menstrual cramps
  - headache            ■ the common cold
- temporarily reduces fever

**Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take more than 6 caplets in 24 hours, which is the maximum daily amount

- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening    ■ blisters    ■ rash

If a skin reaction occurs, stop use and seek medical help right away.

**Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are allergic to acetaminophen or any of the inactive ingredients in this product

**Ask a doctor before use if you have liver disease**

**Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin**

**Stop use and ask a doctor if**

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition. ▶

**Drug Facts (continued)**

If pregnant or breast-feeding, ask a health professional before use.

**Keep out of reach of children.**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Directions**

■ do not take more than directed (see overdose warning)

adults and children 12 years and over

- take 2 caplets every 8 hours with water
- swallow whole; do not crush, chew, split or dissolve
- do not take more than 6 caplets in 24 hours
- do not use for more than 10 days unless directed by a doctor

children under 12 years

- do not use

**Other information**

- store at 20-25°C (68-77°F)
- do not use if printed foil under cap is broken or missing
- meets the requirements of USP Dissolution Test 2

**Inactive ingredients** carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, stearic acid, titanium dioxide

**Questions or comments?** 1-888-423-0139

Contains No Aspirin

U.S. Patent 7,897,172





5S178 88 C3

## TOPCARE 8 HOUR PAIN RELIEF

acetaminophen tablet, film coated, extended release

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-369
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

### Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

### Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	L544
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-369-78	1 in 1 CARTON	04/05/2017	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA075077	04/05/2017		

**Labeler** - Topco Associates LLC (006935977)

Revised: 12/2019

Topco Associates LLC